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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ONYX PHARMACEUTICALS, INC.,

Plaintiff,

v.

BAYER CORPORATION, et al.,

Defendants.

Case No. CV 09 2145 MHP

BRIEF IN SUPPORT OF BAYER'S MOTION FOR SUMMARY JUDGMENT

HEARING DATE: APRIL 25 AT 2 P.M.

PUBLIC REDACTED VERSION

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STATEMENT OF ISSUES TO BE DECIDED

1. Whether Bayer Corp., Bayer HealthCare LLC, Bayer Schering Pharma AG and Bayer AG (collectively, "Bayer") are entitled to summary judgment that regorafenib (also called "DAST") is not a Collaboration Compound under the plain language of the Collaboration Agreement between Bayer and Onyx Pharmaceuticals, Inc., given that DAST was not tested by Bayer until late 2002—more than three years after the expiration of the Collaboration Agreement's Research Term.

2. Whether Onyx's contention that DAST should be considered a Collaboration Compound is barred by the statute of limitations, given that, as a matter of law, Onyx had constructive notice of Bayer's research on DAST more than four years before filing its lawsuit.

3. Whether Onyx's contention that Bayer blocked development of Nexavar by not running two specific clinical trials with Nexavar for the treatment of breast cancer and colorectal cancer (herein referred to as the "Breast AI trial" and the "CRC KRAS trial"), for which Onyx seeks future projected lost profits damages, is barred by the doctrines of waiver and estoppel, given that Onyx previously agreed not to run the two trials it now accuses Bayer of blocking.

4. Whether Onyx's contention that Bayer blocked development of Nexavar by not pursuing a Breast AI trial for registration in Europe fails, since it is undisputed that Bayer has agreed to fund and support the proposed Breast AI trial underlying Onyx's damages claim.

5. Whether Onyx's claim for future projected lost profit damages relating to the alleged "cannibalization" of Nexavar through potential "off-label" prescriptions of DAST is cognizable under the Collaboration Agreement, given that any potential "competition" through off-label prescriptions (the promotion of which Bayer prohibits) would not occur until at least 2011, more than ten years after the Collaboration Agreement's non-compete term expired.

6. Whether Onyx's claims for future projected lost profit damages are improperly speculative and not reasonably certain under California law, where Onyx admits there is a 43 percent likelihood that it has suffered no damages on each of its claims regarding the Breast AI trial, the CRC KRAS trial, and potential "cannibalization" of Nexavar.

INTRODUCTION

In April 1994, Bayer and Onyx entered into a Collaboration Agreement. One goal was to develop cancer-fighting compounds called *raf*-inhibitors that would inhibit cancer growth by a blocking a cellular signaling path called the *ras*-pathway. Bayer and Onyx agreed to conduct joint research for nearly five years, until January 31, 1999. After that, both companies would be free to pursue independent research and development of *raf*-inhibitors.

The collaboration was a success. In 1998, Bayer scientists synthesized and tested a *raf*-inhibitor, sorafenib. Bayer and Onyx developed sorafenib and commercialized it in December 2005 under the commercial name Nexavar®. Nexavar has extended the lives of liver and kidney cancer patients worldwide. Bayer and Onyx now invest [redacted] Euros annually in clinical research to extend Nexavar's reach to additional tumors. Together, Bayer and Onyx have run more than thirty Phase 2 and Phase 3 clinical trials on Nexavar, with over fifteen currently underway. Nexavar is the most important compound in Bayer's oncology portfolio.

After nearly five years of collaborative research, both Bayer and Onyx began working independently to develop new cancer drugs outside the collaboration. Onyx is developing several different anti-cancer compounds, four of which have undergone clinical trials in humans. In late 2002, more than three years after the conclusion of the collaboration's Research Term, Bayer initiated research to develop a second-generation *raf*-inhibitor. In late 2002, Bayer synthesized and tested a new compound called regorafenib, also known as DAST. Like Onyx's compounds, DAST is in clinical trials, but has not been approved by the FDA.

Unsatisfied with Nexavar's success and its own subsequent development efforts, Onyx now claims that it is entitled to ownership in DAST as well. Onyx learned of DAST years before bringing this lawsuit in May 2009, but sat silent until learning of promising clinical data.

Onyx's first three claims (for breach of contract, breach of the covenant of good faith and fair dealing and breach of fiduciary duty) assert identically that Bayer failed to treat DAST as a Collaboration Compound and "undermined" and "prejudiced" the value of Nexavar through its development of DAST. (Dkt#50, 2d Am. Compl. at 13-15) Onyx claims that Bayer blocked the development of Nexavar in new indications to favor Bayer's interest in DAST, and that DAST

will improperly cannibalize Nexavar profits. Onyx's fourth claim seeks a declaration that DAST is a Collaboration Compound to which Onyx is entitled an ownership interest. (*Id.* at 16-17) All told, Onyx claims an ownership interest in DAST and [redacted] in additional damages.

Onyx's claims fail as a matter of law because:

(1) DAST is not a Collaboration Compound under the express terms of the Agreement;

(2) Onyx's claims to the contrary are barred by the statute of limitations;

(3) Onyx has waived, and is estopped from pressing, claims that Bayer "blocked" the development of Nexavar in two indications (a colorectal cancer and breast cancer clinical trial for the U.S.) because it is undisputed that Onyx agreed not to pursue those indications;

(4) Bayer has agreed to go forward in the remaining indication (a breast cancer clinical trial for European registration) that Onyx claims Bayer "blocked";

(5) the Agreement's non-compete provision expired over a decade ago, so Onyx cannot assert a claim for cannibalization of Nexavar sales through off-label DAST prescriptions; and

(6) Onyx cannot prove any damages with reasonable certainty required by California law.

I. BACKGROUND OF THE BAYER-ONYX COLLABORATION

A. The Parties

Bayer HealthCare is an international pharmaceutical company focusing on the research, development and manufacture of pharmaceutical products, including oncology products.[1] (Ex. 1)[2] Onyx is a biotechnology company located in Emeryville, California, now focused on the development of oncology drugs. (Dkt#50, 2d Am. Compl. ¶6) In 1993, Bayer and Onyx began discussing a potential collaboration involving a new type of anti-cancer compounds called targeted therapies. (McCormick Dep. 54:10-13, Ex. 2) These discussions culminated in the 1994 Collaboration Agreement at the heart of this lawsuit. (Ex. 3)

[1] Onyx named Bayer Corp., Bayer HealthCare LLC, Bayer Schering Pharma AG and Bayer AG as defendants in this action. They are referred to collectively as "Bayer" in this brief. Bayer's summary judgment arguments apply to each entity.

[2] All references to "Ex. __" in this brief will be to Exhibits to the Swanson Declaration.

B. Targeted Therapy Oncology Drugs

Targeted therapies such as Nexavar and DAST inhibit or destroy specific molecules (or targets) in cellular pathways that promote tumor growth. Earlier cancer treatments, such as radiation and chemotherapy, destroy both cancerous and non-cancerous cells. Because destroying non-cancerous cells causes deleterious side effects, targeted therapies can provide effective treatment with lower toxicity than earlier therapies. (Ex. 4)

Nexavar and DAST belong to a sub-class of targeted therapy drugs called kinase inhibitors. Kinases are enzymes, proteins that increase the rate of chemical reactions. One function of certain kinases—including *raf*—is to promote and regulate cellular growth by passing signals along a cellular pathway to the cell nucleus. Since cancerous cells grow in an unregulated fashion, targeting and inhibiting specific kinases can slow cancer growth. (*Id*.)

In the early 1990's, both Bayer and Onyx had libraries of compounds. (McCormick Dep. 51:8-22, Ex. 2) But neither company had identified or developed any kinase inhibitors that were effective in treating cancer. (Renton Dep. 28:8-19, Ex. 5; Ex. 6 at 5) Bayer and Onyx hoped that by taking advantage of each other's relevant expertise, they could jointly identify or develop such a drug. (McCormick Dep. 53:3-54:13, Ex. 2; Ex. 7 at -353-54)

C. Bayer and Onyx Negotiate and Agree to Contract Terms

Following negotiations, Bayer and Onyx executed the Agreement in April 1994. (Ex. 3) The Agreement has been amended twice, once in 1996 and once in 1999. (Exs. 8, 9) The Agreement's key terms, for purposes of this motion, are discussed below.

1. The "Research Term"

Bayer and Onyx negotiated how long they would work cooperatively and without competition, and when both would be free to engage in their own independent (and potentially competitive) research and development. They negotiated a five-year "exclusivity" period—the "Research Term"—during which the parties would not compete in the field of *raf*-inhibition. (Ex. 3 at §§1.45, 26.3; Brandau Dep. 236:11-237:11, Ex. 10) That term ended on January 31, 1999. (*Id.*) Onyx recognized that it would be "competitors with Bayer at the end of term," and thus should "plan for aggressive independent development" after that time. (Ex. 11 at -820-21)

2. Governance

A Joint Research and Development Committee ("JRDC")—later morphed into the Executive Committee ("EC")—had certain decision-making authority over research and development for the collaboration.[3] The Agreement states that the JRDC/EC "shall operate by consensus. Any deadlock shall be referred to the designated executive officers of [Bayer] and Onyx pursuant to Article 25." (Ex. 3 at §3.1) Under Article 25, the designated executive officers of Bayer and Onyx must "negotiate in good faith to achieve a resolution of the dispute referred to them." (*Id.* §25.1) Only if the executives cannot resolve the dispute may Bayer or Onyx "invoke any other remedies available to it in law or equity"—such as seeking damages in a lawsuit. (*Id.*)

3. Collaboration and Post-Collaboration Compounds

Under Section 1.9 of the Agreement, any compound "discovered, identified or synthesized" and "recognized for its activity for inhibiting Ras Function" prior to January 31, 2000 (the "first anniversary of the end of the Research Term") would be considered a "Collaboration Compound." (Exs. 3, 9 at §1.9) Section 1.9 of the Agreement as amended defines "recognized" as follows:

> As used herein, the activity of a composition of matter for inhibiting a target within the Residual Field of Collaborative Research will be "recognized" if it satisfies that standard for a ras positive set forth in Exhibit D, or other specific activity in a particular assay or assays within the Residual Field of Collaborative Research established by the JRDC from time to time pursuant to Section 6.3.

(Ex. 9 at §1.9)

The referenced Exhibit D—entitled "Measured Activity Qualifying as 'Positive Inhibition in the Field'"—mandates experimental biological tests to measure and quantify a compound's activity in both a primary assay and a selective screen.[4] (Ex. 8 at Ex. D) For each test, Exhibit D

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[3] The companies later created a group known as the Joint Development Committee, or "JDC," which is responsible for, among other things, creating development plans to present to the EC for approval and executing clinical trials. (Yancey Dep. 42:4-43:1, Ex. 17)

[4] Section 1.9 in the original Collaboration Agreement mistakenly refers to Exhibit E. That is a typographical error (Jones Dep. 128:17-24, Ex. 12), which was corrected in the amendments. (Exs. 8, 9 at §1.9)

describes the requisite "measured activity": a measured IC50 of less than 10 µM in the primary assay, and a measured IC50 of greater than 10 µM in the selective screen. (*Id.*)[5]

Section 6.3, referenced in the definition of Collaboration Compound, makes it clear that "measured activity" is required for a compound to qualify as a Collaboration Compound:

> The JRDC shall specify the assays and the level of *measured activity* under such assays in the Field of Collaborative Research that shall be required by the Parties to establish that a specific composition of matter exhibits a *sufficient level of activity* in inhibiting Ras Function or in modulating the activity of the Additional Cancer Targets and/or targets within the Collaboration Cancer Programs, as applicable, *to qualify as a Collaboration Compound under Section 1.9*. The initial standards of *measured activity* for identifying a Collaboration Compound are set forth in Exhibit D.

(Ex. 8 at §6.3, emphasis added)

The parties expressly considered the value of subsequent independent research utilizing the "know-how" obtained during the Research Term. (Brandau Dep. 238:20-40:10, Ex. 10) They agreed that for a period of four years after the Research Term, any compound "contained within a chemical genus as defined in any pending or issued claim of any unexpired [Bayer] Patent or Onyx Patent . . . as to which at least one member of such chemical genus is a Collaboration Compound" that is "recognized for its activity for inhibiting Ras Function" would be a "Post Collaboration Compound" and, if commercialized, subject to royalty payments. (Ex. 3 at §1.39) In an amendment to the Agreement, the term for a Post-Collaboration Compound was shortened to three years after the end of the Research Term, which is January 31, 2002. (Ex. 9 at §1.39)

Under the Agreement, neither company has rights in any compound independently developed by the other that was "recognized" after January 31, 2002 for *raf*-inhibiting activity.

4. Non-compete clause

Section 26.3 of the Agreement is a non-compete clause, which states that "*[d]uring the Research Term*"—until January 31, 1999—the companies will not conduct independent research or development of kinase inhibitors. (Ex. 3 at §26.3) The Agreement does not restrict competition after January 31, 1999.

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[5] An IC50 is a measurement of the potency of a compound; a µM (micromolar) is the unit of measurement. A lower IC50 value in the primary assay signifies a more potent compound.

II. NEXAVAR

A. Bayer Chemists Synthesize Nexavar

Shortly after executing the Agreement, Bayer and Onyx began running compounds through assays to test for activity. (McCormick Dep. 90:6-91:8, Ex. 2; Scott Dep. 24:14-23, Ex. 13; Bollag Dep. 133:21-134:7, Ex. 14) The companies found lead compounds from this screening, but none displayed a level of therapeutic activity high enough to develop into a commercial compound. (Lowinger Dep. 71:17-72:3, 79:21-82:13, Ex. 15; Riedl Dep. 18:4-19:12, Ex. 16; McCormick Dep. 102:8-104:2, Ex. 2) Bayer chemists began creating novel compounds through a process called "combinatorial chemistry": taking an existing compound and randomly mixing up its components (*e.g.*, its chemical rings and structures) and adding new ones. (Ex. 18 at -510-511; Ex. 19 at -972; Lowinger Dep 82:21-84:7, Ex. 15; Riedl Dep. 20:20-22:15, Ex. 16) This work generated a new lead compound, from which Bayer chemists ultimately synthesized sorafenib in April 1998. (Ex. 20 at -916; Ex. 21 at -246) Based on its measured activity, Bayer and Onyx moved sorafenib into clinical development in 1999 at the end of the Research Term. (Ex. 22 at -144-46; Bollag Dep. 214:19-215:19, Ex. 14; Wilhelm Dep. 76:10-77:3, Ex. 23)

Just prior to the end of the Research Term, in a meeting of Bayer and Onyx scientists in September 1998, Bayer chemists presented a slide containing a single chemical structure, sorafenib, and a variety of proposed hypothetical changes to the sorafenib chemical backbone. (Ex. 24 at -913) One of the thousands of hypothetical changes contemplated on the slide was the addition of a fluorine atom to the sorafenib molecule, the structure that Bayer later synthesized as DAST. (*Id.*) DAST is not a naturally-occurring substance, and it is undisputed that neither Bayer nor Onyx made or tested DAST before January 31, 2002. (Ex. 25 at -080; Ex. 26 at -351; Scott Dep. 87:19-88:15, Ex. 13; Adnane Dep. 73:7-76:10, Ex. 27)

B. Bayer and Onyx Develop Nexavar in Multiple Cancer Indications

Based on positive results from a Phase 3 clinical trial, the FDA approved Nexavar for first-line kidney cancer treatment in 2005 (the first treatment a cancer patient receives is referred to as first-line treatment; if the disease progresses, a patient will undergo second-line (then third- and fourth-line) treatment). (Exs. 28, 29) Two years later, based on additional positive clinical

results, the FDA approved Nexavar for the treatment of liver cancer. Bayer and Onyx have funded numerous clinical trials in different tumor types, including colorectal, breast, melanoma, lung and thyroid. (Ex. 30 at 2-3; Ex. 31 at -441-444; Ex. 32 at -162-67)

This effort is ongoing. Bayer and Onyx together have budgeted [redacted] Euros to fund the development of Nexavar in 2011. (Ex. 33 at No. 23) [redacted]. (Moeller Dep. 177:5-78:12, Ex. 34) From 2007-2010, Bayer spent approximately [redacted] on Nexavar as it spent on DAST, and intends to spend [redacted] on Nexavar as on DAST in 2011. (Ex. 33 at No. 23)

While the budget for Nexavar development is large, it is not unlimited. In evaluating whether to run clinical trials (which can cost in excess of $100 million each), Bayer and Onyx evaluate the probability that a specific trial will lead to regulatory approval of a compound—an estimate they call "probability of technical and regulatory success," or "PTRS." PTRS measures the perceived likelihood that a given trial will satisfy the designated trial endpoint and obtain regulatory approval. (Ex. 35 at ¶49)

C. Clinical Trials in Colorectal Cancer and Breast Cancer

Nexavar clinical trials in colorectal cancer (CRC) and breast cancer are of particular relevance to Onyx's claims in this lawsuit.

1. CRC clinical trials

In 2008 and 2009, Bayer and Onyx evaluated two potential clinical trials in colorectal cancer: (1) a Phase 2b clinical trial of Nexavar in combination with a chemotherapy "cocktail" called FOLFOX for the first-line treatment of patients with CRC (the "RESPECT trial"), and (2) a Phase 3 clinical trial of Nexavar with the chemotherapy "cocktail" FOLFIRI for second-line treatment in patients with a mutated gene (called the KRAS gene) and whose colorectal cancer had progressed following first-line treatment (the "CRC KRAS trial"). (Ex. 36 at -007, -013)

In December 2008, the companies agreed to move forward with the Phase 2 RESPECT trial on CRC first-line treatment. (Ex. 37 at -619) They continued to evaluate whether to conduct the CRC KRAS trial. The PTRS agreed to by Bayer and Onyx for the CRC KRAS trial was [redacted]

[redacted] (Ex. 38 at -407) The companies estimated that the total costs to run this trial were approximately [redacted] Euros. (*Id.*) Based on high trial costs and the low probability of success, Bayer felt that the business case for the CRC KRAS trial was not viable and that the trial should not proceed. (*Id.*; Ex. 39 at -654) Onyx favored the trial, despite low odds and high costs. (*Id.*)

Following months of discussions, during a September 2009 EC meeting, Onyx agreed with Bayer not to move forward with the CRC KRAS trial. According to the final minutes of that meeting, "Tony [Coles, Onyx's CEO] led off the conversation around Nexavar in CRC by sharing that Onyx agrees not to move forward with the CRC 2nd line registration trial at this time. He mentioned that the company should now focus on the most cost efficient way to move forward with the CRC 1st line P2 trial," or RESPECT trial. (Ex. 40 at -657) Dr. Coles confirmed that agreement in his deposition. (Coles Dep. 203:17-22, Ex. 41)

2. Breast cancer clinical trials

In 2006, Bayer and Onyx agreed on a program for multiple Phase 2 clinical trials on the combination of Nexavar with other drugs to treat breast cancer. (Yancey Dep. 75:18-76:10, Ex. 17; Ex. 42 at -361) As a result of promising results from one of those trials, Bayer and Onyx are running a Phase 3 clinical trial (the "RESILIENCE" study) using the combination of Nexavar and a compound called capecitabine to treat breast cancer. (Ex. 43 at 5; Lokker Dep. 137:16-38:16, Ex. 44) The program initially included a planned Phase 2 trial for the use of Nexavar with a form of hormone therapy called an Aromatase Inhibitor ("AI") for the treatment of breast cancer. Due to feasibility/enrollment problems, that trial was discontinued. (Yancey Dep. 94:14-95:6, Ex. 17; Ex. 45 at -340)

Despite the lack of a Phase 2 trial, Bayer and Onyx discussed the possibility of running a larger global Phase 3 trial combining Nexavar and an AI to treat breast cancer (the "Breast AI trial"). The proposed end point of this trial was progression-free survival (PFS)—in other words, that patients taking the Nexavar combination therapy went longer without tumor progression. (Ex. 46 at -517) Given the FDA's preference for a different measure in assessing oncology products—a showing of overall survival (OS) benefit—Bayer and Onyx agreed to present their proposed

trial plan to the FDA prior to trial initiation to obtain feedback on, among other things, the acceptability to the FDA of the proposed PFS endpoint. (Ex. 47 at 3-5; Ex. 48 at -280-82)

In September 2010, in response to Bayer's and Onyx's request for guidance, the FDA stated, *inter alia*, that a PFS endpoint was not acceptable for approval in Breast AI, and that "[t]he primary endpoint should be [OS]." (Ex. 48 at -282-83) The FDA stated that "if OS is the primary endpoint and a pre-specified interim analysis uncovers a striking improvement in PFS," only then would the FDA discuss "the regulatory implications of such results." (*Id*. at -282)

Given the FDA's negative feedback, the Bayer-Onyx Joint Development Committee agreed in October 2010 that it was "not technically feasible" to implement the FDA's required OS endpoint in the proposed Breast AI trial. (Lokker Dep. 128:3-7, Ex. 44; Ex. 49 at 9-12) The Executive Committee agreed. (Love Dep. 55:19-56:6, 60:21-61:4, 61:8-15, Ex. 50) After a few months of discussion on whether to conduct a Breast AI trial (without incorporating the FDA-requested changes) for registration in Europe only, Bayer has agreed to this trial, based on feedback that European regulatory agencies are more likely to accept a PFS endpoint. (Ex. 51)

III. DAST

A. Bayer Independently Develops DAST

In the summer of 2002—more than three years after the end of the Research Term—Bayer independently launched a new project called "RKI2" (Raf-kinase inhibitor 2), through which it sought to develop a second-generation *raf* kinase inhibitor. (Scott Dep. 110:19-11:1, Ex. 13; Riedl Dep. 227:17-23, Ex. 16; Dumas Dep. 199:13-200:22, Ex. 52) As part of the RKI2 project, Bayer considered numerous modifications to the Nexavar compound. (Ex. 53 at -451-55) During early clinical trials, it had become apparent that sorafenib exhibited low bioavailability, which meant that the body could absorb only a limited amount of sorafenib. (*Id.* at -433; Scott Dep. 110:19-111:25, Ex. 13) Increasing the dosage of sorafenib beyond a certain level did not increase the amount of drug in the bloodstream. (*Id.*) Bayer hypothesized that this low bioavailability resulted from sorafenib having low solubility. (*Id.*) In an effort to improve upon these perceived shortcomings, Bayer synthesized and tested hundreds of new compounds in 2002. One of those compounds was DAST, which Bayer chemists first synthesized on November 22, 2002 and tested

in a primary assay on December 10, 2002. (Ex. 25 at -080; Ex. 26 at -351) While DAST did not exhibit substantially increased solubility over Nexavar, it was significantly more potent, especially in the crucial *in vivo* animal model tests. (Ex. 54 at -818-19)

In the fall of 2003, Bayer decided to pursue commercialization of DAST. (Ex. 54) Bayer is currently running Phase 3 trials for 3rd/4th line CRC and 3rd/4th line gastrointestinal stromal tumor (GIST). (Ex. 33 at No. 9) Bayer is not running any Phase 3 trials for DAST in breast cancer or 1st or 2nd line CRC. (Gelder Dep. 126:8-12, 192:15-93:2, 196:25-97:15, Ex. 55)

B. Onyx Learns of DAST

Following the synthesis of DAST in 2002, Bayer sought to protect its intellectual property in that compound through the filing of various patent applications globally, including in the U.S. and European patent offices. Bayer's Patent Cooperation Treaty application for DAST was published on February 3, 2005. (Ex. 56) It shows the chemical structure for DAST on the front page and states that the compound "is a potent inhibitor [of] raf kinase" and used for "treatment and prevention of … hyper-proliferative disorders, and angiogenesis disorders, including cancer." (*Id.* at -767, -780) Bayer's U.S. patent application was published on February 17, 2005. (Ex. 57) Onyx learned of DAST thereafter in December 2005. (Post Dep. 24:17-26:3, Ex. 58; Giotta Dep. 120:23-22:11, Ex. 59)

C. Onyx Sues Bayer Claiming Rights to DAST

Onyx filed this lawsuit in May of 2009. Onyx's operative complaint, its second amended, asserts four claims for relief: breach of contract (first claim for relief); breach of implied covenant of good faith and fair dealing (second claim for relief); breach of fiduciary duty (third claim for relief); and declaratory relief (fourth claim for relief).

For each of the first three claims, Onyx asserts identical allegations of what constitutes Bayer's alleged breach: "(a) failing to disclose [Bayer's] research and development plans for [DAST]; (b) failing to treat [DAST] as a Collaboration Compound; (c) undermining the value of sorafenib through [Bayer's] development of [DAST]; and (d) prejudicing the value of sorafenib by reason of [Bayer's] interest in other drugs, including [DAST]." (Dkt#50, 2d Am. Compl. at 13-16) Onyx's fourth claim seeks a declaration that DAST is a Collaboration Compound to which

Onyx is entitled an ownership interest, which relates to items (a) and (b) in Onyx's list of breaches in its first three claims. (*Id.* at 16-17)

Onyx seeks [redacted] dollars in damages, which relate to items (c) and (d) in Onyx's list: [redacted] for Bayer's alleged blocking of the development of Nexavar for the CRC KRAS indication, [redacted] for Bayer's alleged blocking of the development of Nexavar for the Breast AI indication, and [redacted] for the "cannibalization" of Nexavar sales by DAST. (Ex. 60 at ¶¶13.2, 13.4)

SUMMARY JUDGMENT STANDARDS

Summary judgment is warranted where the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c). To avoid summary judgment, Onyx must "produce significant probative evidence, by affidavit or as otherwise provided in FRCP 56, supporting its claim that a genuine issue of material fact exists." *Scottsdale Ins. Co. v. OU Interests, Inc.*, No. C05-0313 VRW, 2005 WL 2893865, at *3 (N.D. Cal. Nov. 2, 2005).

ARGUMENT

I. BAYER IS ENTITLED TO SUMMARY JUDGMENT THAT DAST IS NOT A COLLABORATION COMPOUND AS A MATTER OF LAW

DAST is not a Collaboration Compound. Therefore, Onyx's first three claims fail to the extent they seek relief based on a theory that DAST is a Collaboration Compound, and Onyx's fourth claim fails entirely. In addition, Onyx is barred by the statute of limitations from raising any claims that DAST is a Collaboration Compound.

A. DAST is Not a Collaboration Compound

In a breach of contract action, "[s]ummary judgment is appropriate when the contract terms are clear and unambiguous, even if the parties disagree as to their meaning." *United States v. King Features Entm't, Inc.*, 843 F.2d 394, 398 (9th Cir. 1988). The interpretation of a contract is a matter of law—including whether the contract is ambiguous. *See International Union of Bricklayers & Allied Craftsman Local Union No. 20 v. Martin Jaska, Inc.*, 752 F.2d 1401, 1406

(9th Cir. 1985). Onyx's claims for breach of the covenant of good faith and fair dealing and breach of fiduciary duty are subject to the same standards as its breach of contract claim since there is no independent duty outside of that set forth in the detailed 63-page (plus attachments) contract negotiated by sophisticated companies. *See Guz v. Bechtel Nat'l Inc.*, 24 Cal. 4th 317, 327 (2000) ("[W]here [the] breach of an actual term is alleged, a separate implied covenant claim, based on the same breach, is superfluous.").

1. DAST is not a Collaboration Compound under the plain and unambiguous language of the Agreement

The starting point for contract construction is the plain language of the agreement. *Winet v. Price*, 4 Cal. App. 4th 1159, 1166 (1992); Cal. Civ. Code § 1639.[6] To be considered a Collaboration Compound under Section 1.9 of the Agreement—and thus subject to joint ownership—a composition of matter must meet two separate and distinct requirements. First, the compound must have been "discovered, identified or synthesized" prior to January 31, 2000, one year after the end of the Research Term. (Exs. 8, 9 at §1.9) Second, under Sections 1.9, 6.3, and Exhibit D, the activity of such a compound must be measured to determine if it exhibits "recognized" activity. (Exs. 8, 9 at §§1.9, 6.3, Ex. D)

Undisputed evidence shows that DAST does not meet at least the second independent requirement. The Agreement specifies with particularity what is required to constitute "recognized" *raf* inhibitory activity: a compound must display "measured activity" in two separate biological assays, a primary assay and a selective screen. (Exs. 8, 9 at §1.9, Ex. D) But DAST was not measured for its *raf* activity in the primary assay until December 10, 2002, almost three years after the deadline for treatment as a Collaboration Compound and almost one year after the deadline for a Post-Collaboration Compound. (Ex. 26 at -351; Adnane Dep. 73:7-76:10, Ex. 27) DAST has never been tested in the requisite "selective screen." (Adnane Dep 9:15-10:7, 11:15-17, Ex. 27) Because DAST was never "recognized" for *raf*-activity, as that term is defined in the Agreement, within the time limits set by the Agreement, it is neither a Collaboration

[6] California law controls under Section 28.13 of the Collaboration Agreement. (Ex. 3)

Compound nor a Post-Collaboration Compound as a matter of law. A timeline comparing the date of first testing of DAST to the relevant deadlines in the Agreement is attached as Appendix A.

2. The extrinsic evidence supports the plain meaning

The Court may consider extrinsic evidence to determine "whether the offered evidence is relevant to prove a meaning to which the language of the instrument is reasonably susceptible." *Pacific Gas & Elec. Co. v. Thomas Drayage*, 69 Cal. 2d 33, 37 (1968). "[W]ith respect to extrinsic evidence, the relevant point in time for contract interpretation is the date of formation." *Flintkote Co. v. Gen. Accident Assur. Co. of Can.*, 410 F. Supp. 2d 875, 887 (N.D. Cal. 2006). "However, after considering the evidence, the court may then exclude it if it 'tends to prove a meaning of which the language [of the contract] is not reasonably susceptible.'" *Jones-Hamilton Co. v. Beazer Materials & Servs.*, 973 F.2d 688, 692-693 (9th Cir. 1992) (citation omitted). In that event, "'the case may then be disposed of by summary judgment.'" *Id.* (citation omitted).

The extrinsic evidence here—based on the drafting history and discussions between negotiators from the companies—supports the plain meaning of the Agreement that a compound is not "recognized" until there is the requisite specified "measured activity." The definition of a Collaboration Compound requiring a "composition of matter" that was "recognized" for its activity under the standards set forth in Exhibit D was a narrowing of the definition from earlier exchanged drafts with broader definitions of Collaboration Compound.

A July 1993 Onyx draft Term Sheet (which preceded drafts of the Agreement) defined "Collaboration Compound" as a compound "*conceived* by the parties in the course of the research, or within one year following the end of the Research Term by any person who worked on the research (all as defined by composition-of-matter patents filed by the parties)." (Ex. 61 at -375) (emphasis added) A compound "conceived" by the companies is broad enough to include hypothetical compounds never made or tested. (McCormick Dep. 56:19-57:3, Ex. 2) The companies did not agree to that definition.

In December 1993, Onyx proposed a different definition of Collaboration Compound, which added not only the "discovered, identified or synthesized" and "recognized" language, but also a separate way for a composition of a matter to be a Collaboration Compound: if it is

"contained within any chemical genus . . . as defined in any pending or issued claim of any unexpired" patent relating to the collaboration. (Ex. 62 at -018-19) In a meeting the next month, the companies discussed this proposed definition and "how to proceed with compounds that physically do not exist at present and, for this reason, have never been tested on ras activity so far but are patent protected." (Ex. 63 at -349) The companies developed a matrix, reflected in Exhibit A(3) to the Agreement, that shows that for compounds included within a genus patent, "each party is free in using their compounds under their own patents" after the passage of four years (later changed to three years by amendment) after the Research Term. (Ex. 63 at -353; Ex. 3 at -877; Jones Dep. 119:16-19, Ex. 12) This is significant because DAST is a compound that is covered by a chemical genus patent but not tested on *raf* activity during the Research Term or the three years that followed. (Ex. 64 at -079; Ex. 26 at -351; Adnane Dep. 73:7-76:10, Ex. 27)

The negotiators on both sides have testified that Bayer rejected the definition and told Onyx that it was too broad. Robert Jones, an attorney for Cooley LLP (which also represents Onyx in this lawsuit), who negotiated and drafted the Agreement for Onyx, testified:

> And Dr. Brandau, you know, said that's too broad. And so we worked then to define a revised definition of collaboration compound. The Bayer argument was that the issue with the genus patents was that it included molecules whose identity and activity were too—were not sufficiently related to this discovery collaboration and that because—because in order to find those other molecules in the future, it would take further effort and money after the end of the research term, that it was too sweeping to include the genus patents.

(Jones Dep. 117:15-25, Ex. 12; *see also* Brandau Dep. 200:21-201:1, Ex. 10 (confirming that Collaboration Compounds had to reflect "the scientific work performed during the research term") This proposed broad provision was removed from the definition of Collaboration Compound.[7] (Jones Dep. 125:11-15, Ex. 12)

In the final version of the Agreement, the only remaining definition of a Collaboration Compound was Section 1.9's narrower requirement that a Collaboration Compound was a

[7] The reference to the chemical genus was thereafter included in the definition of Post-Collaboration Compound but with a limitation on the timing so that the activity must be "recognized" within the 3 year period following the expiration of the Research Term.

composition of matter "discovered, identified, or synthesized" and "recognized" for its activity through "measured activity" according to the requirements of Exhibit D. (Ex. 3 at §1.9, Ex. D)

Dr. Brandau, now retired from Bayer, explained that the companies specifically discussed the requirement that to be "recognized" there had to be tests to measure activity:

> Q: How did you determine whether a compound in question met the standards which we have defined in the particular Exhibit which refers to the biological activity?
>
> A: We have to run the assays.
>
> Q: Was that Bayer's intention in including that provision in the final Collaboration Agreement?
>
> A: Yes, it was.
>
> Q: And did you discuss and express that intention to the individuals at Onyx Bayer's belief that a compound must be tested before it could be considered a Collaboration Agreement compound?
>
> A: Yes, it was fully understood and accepted.
>
> Q: My question is; is it something that you discussed and expressed to Onyx?
>
> A: Yes.
>
> Q: Did anyone from Onyx [ex]press any disagreement or disapproval of Bayer's intent?
>
> A: No.

(Brandau Dep. 243:4-21, Ex. 10)

In sum, the extrinsic evidence is consistent with the plain text of the Agreement. Section 1.9 is not "reasonably susceptible" to a definition of Collaboration Compound that includes hypothetical compounds not actually measured in the required Exhibit D assays.

B. Onyx's Claim that DAST is a Collaboration Compound is Barred by the Relevant Statute of Limitations

Under California law, the limitations period for actions grounded in breach of contract and breach of fiduciary duty is four years. Cal. Civ. Pro. §§ 337, 343. The limitations period begins to run when the plaintiff has actual or constructive notice of the facts giving rise to the claim. *General Bedding Corp. v. Echevarria*, 947 F. 2d 1395, 1397 (9th Cir. 1991).

Onyx gained constructive notice that Bayer was developing DAST from published patent applications in February 2005. Issuance of a patent constitutes notice to the world of its existence.

Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co., 297 U.S. 387, 393 (1936); *General Bedding Corp.*, 947 F. 2d at 1397-98. Several courts have specifically found that the "issuance of a patent gives a plaintiff constructive notice of its claims if the patent reveals information sufficient to alert a reasonable person of the need to inquire further" and begins the period for the statute of limitations. *International Business Machines Corp. v. Zachariades*, No. C 91-20419 JW, 1993 WL 443409, at *2 (N.D. Cal. Oct. 27, 1993), *aff'd in part and rev'd in part*, 70 F.3d 1278 (9th Cir.1995); *see also Hartley Pen Co. v. Lindy Pen Co.*, 16 F.R.D. 141, 157 (S.D. Cal. 1954) (ruling notice of the issuance of a patent started accrual of statute of limitations).[8]

Since 2000, patent applications are also subject to official publication by the United States Patent Office, providing notice of the description and claims of the application. 35 U.S.C. § 122. International patent applications are also officially published. There is no meaningful difference in terms of constructive notice between publication of patent applications and the issuance of patents. Both are published by the US PTO or corresponding international body and give notice of the contents of the patent or patent application.

Here, the international patent application for DAST was published on February 3, 2005, and the United States patent application for DAST was published two weeks later, on February 17, 2005. (Exs. 56, 57) Both published patent applications show, on the front page of the applications, the chemical structure of DAST. (*Id.*) Both describe the field of the invention as relating to novel compounds for treating diseases mediated by *raf* kinase signaling (including cancer), and that the compound is a potent *raf* kinase inhibitor. (Ex. 56 at -780; Ex. 57 at -628) With the publication of the patent applications in February 2005, Onyx had constructive notice of their contents, including the structure of DAST, its function as a *raf* kinase inhibitor, and its

[8] Although the 9th Circuit has ruled that an issued patent is constructive notice of its contents, at least one court in this district found that holding not to be controlling. *See, e.g., Applera Corp. v. Illumina, Inc.*, No. C 07-02845 WHA, 2008 WL 927963 (N.D. Cal. April 4, 2008). Bayer believes the 9th Circuit precedent is clear for this Court that an issued patent provides constructive notice of its contents.

potential for use in the treatment of cancer. Onyx cites the structure of DAST as a key fact in its complaint, calling DAST and Nexavar "fraternal twins." (Dkt#50, 2d Am. Compl. ¶37)

As of February 2005, Onyx had notice of all the facts necessary to alert it of the need to inquire further into whether it had a claim based on Bayer's development of DAST. That is more than four years before Onyx filed its lawsuit. Therefore, Onyx's claims that DAST is a Collaboration Compound are outside the statute of limitations period as a matter of law.

II. BAYER IS ENTITLED TO SUMMARY JUDGMENT THAT IT HAS NOT BREACHED ANY DUTIES OWED TO ONYX

Onyx seeks [redacted] dollars in damages on its claims that Bayer "undermined" and "prejudiced" Nexavar's value—$[redacted] for Bayer's alleged blocking of the development of Nexavar for the CRC KRAS indication, [redacted] for Bayer's alleged blocking of the development of Nexavar for the Breast AI indication, and [redacted] for the "cannibalization" of Nexavar sales by DAST through future off-label prescriptions. (Ex. 60 at ¶¶13.2, 13.4)

Bayer is entitled to summary judgment on the first three claims to the extent they assert that Bayer has undermined or prejudiced the value of sorafenib by development of, and interest in, DAST for three reasons. First, Onyx has waived, and is estopped from asserting, any claims related to the decision not to develop Nexavar in the CRC KRAS indication and the Breast AI indication in the U.S. because it is undisputed that Onyx agreed with that decision. Second, Onyx cannot assert claims for non-development of Nexavar in the Breast AI indication in Europe because it is undisputed that Bayer has agreed to pursue that indication. Finally, Onyx cannot assert claims for cannibalization by DAST of Nexavar sales, because the time period limiting competition between Bayer and Onyx expired more than a decade ago.

A. Onyx's Claims Based on the CRC KRAS Trial and Breast AI Trial for the U.S. are Barred as a Matter of Law by Waiver and Equitable Estoppel

Onyx has waived, and is estopped from asserting, any claim arising from the alleged failure to run the CRC KRAS trial or the U.S. portion of the Breast AI trial. Onyx specifically agreed with Bayer on the decision not to run those trials.

"Waiver is the intentional relinquishment of a known right after knowledge of the facts." *National Union Fire Ins. Co. v. Hilton Hotels Corp.*, No. C-90-2189 MHP, 1991 WL 405182, at *5 (N.D. Cal. May 6, 1991) (citations omitted). Waiver may be express or may be based on "conduct manifestly inconsistent with the intention to enforce a known right." *Oakland Raiders v. Oakland-Alameda County Coliseum, Inc.*, 144 Cal. App. 4th 1175, 1191 (2006) (waiver "may be determined as a matter of law where the underlying facts are undisputed"). Equitable estoppel prevents a party from denying "the existence of a state of facts if he intentionally led another to believe a particular circumstance to be true and to rely upon such belief to his detriment." *Id*. at 1189.

1. Onyx agreed not to pursue the CRC KRAS trial

Onyx now alleges that Bayer breached the Agreement by "block[ing] development of Nexavar as a second-line treatment for colorectal cancer ('CRC') in patients with KRAS mutations ...." (Ex. 60 at ¶5.1) Even if Onyx could present facts supporting this allegation, it has waived and is estopped from asserting this claim based on its prior agreement *not* to proceed with the proposed CRC KRAS trial.

The Executive Committee governs the development of Nexavar. (Ex. 3 at §3.1) The Executive Committee "operate[s] by consensus," and Bayer and Onyx have an equal voting share. (*Id*.; Coles Dep. 32:7-14, Ex. 41; Brege (Onyx 30(b)(6)) Dep. 12:9-13:13, Ex. 79) It is undisputed that in September 2009, following discussions regarding the business case and design of the CRC KRAS trial, Onyx and Bayer agreed at the Executive Committee meeting not to proceed with the proposed CRC KRAS trial underlying Dr. Cockburn's damages analysis. (Ex. 40 at -657; Coles Dep. 203:17-22, Ex. 41; Yancey Dep. 250:23-51:11, Ex. 17) The final minutes from that meeting reflect that Tony Coles, Onyx's CEO, "led off the conversation around Nexavar in CRC by sharing that Onyx agrees not to move forward with the CRC 2nd line registration trial at this time." (Ex. 40 at -657) Dr. Coles admitted that Onyx agreed in September 2009 not to pursue the CRC KRAS trial. (Coles Dep. 203:17-22, Ex. 41) Bayer and Onyx decided instead to focus on the separate RESPECT trial. (Ex. 40 at -657)

Through its previous agreement not to proceed with the CRC KRAS trial, Onyx waived its right to now assert that it was injured by the failure to run that trial. If Onyx believed that the collaboration should pursue the CRC KRAS trial, Onyx was obligated to press its claim before the Executive Committee, and, if necessary, invoke the Agreement's dispute resolution clause (§25.1) if no agreement were reached. Instead, Onyx agreed to abandon the trial. It cannot assert this claim now. *See Oakland Raiders*, 144 Cal. App. 4th at 1191.

Onyx is also estopped from claiming damages based on the decision not to run the CRC KRAS trial. Equitable estoppel applies where: (1) the party to be estopped knows the facts, (2) he intends his conduct to be relied upon, (3) the other party is ignorant of the facts, and (4) the other party has relied upon the conduct to his injury. *In re Gerry*, 670 F. Supp. 276 (N.D. Cal. 1987); *Lix v. Edwards*, 82 Cal. App. 3d 573, 580 (1978). Bayer has established each element of estoppel with undisputed evidence.

First, it is undisputed that Bayer and Onyx engaged in extensive discussions regarding whether to pursue the CRC KRAS trial, and that Onyx agreed not to move forward. (Ex. 40 at -657; Coles Dep. 203:17-22, Ex. 41; Yancey Dep. 250:23-51:11, Ex. 17) Second, Onyx intended Bayer to rely on its representation, because the Executive Committee was the decision-making body for the collaboration. Third, Bayer was ignorant of the fact that Onyx would repudiate its agreement and instead charge Bayer with "blocking" Nexavar's development in CRC KRAS in the pending litigation. Finally, Bayer relied on Onyx's representation to its own detriment. Had Onyx instead demanded to pursue the CRC KRAS trial, and invoked the Agreement's dispute resolution provision, Bayer may have agreed to invest in the trial at that time.

2. Onyx agreed the Breast AI trial was not "technically feasible" for registration in the U.S.

Onyx has waived and is estopped from pressing its claim over not running the Breast AI trial for registration in the U.S. as originally planned. Prior to commencing the Breast AI trial, Bayer and Onyx sought feedback from the FDA regarding the trial design—specifically whether the proposed trial endpoint, progression free survival, was "acceptable for regular approval." (Ex. 48 at -282) The FDA responded that the proposed PFS endpoint was not acceptable, and that the

"primary endpoint should be overall survival." (*Id.*) Based on this feedback, the JDC and EC determined that the proposed Breast AI trial was "no longer technically feasible" for registration in the U.S., but the parties agreed to evaluate whether to pursue such a trial for registration in Europe. (Love Dep. 55:19-56:6, 60:21-61:4, 61:8-15, Ex. 50; Ex. 65 at 5)

After agreeing that the Breast AI trial was not technically feasible for registration in the U.S. and should not be run as originally planned, Onyx cannot now claim that it was damaged by the decision not to run that trial. Onyx's claim related to the U.S. portion of the Breast AI trial is barred by the doctrines of waiver and equitable estoppel, which exist to prevent the sort of gamesmanship reflected in Onyx's claims.

B. Onyx's Claim on the Breast AI Trial for Europe Fails Because Bayer Has Agreed to Proceed with That Trial

Onyx claims [redacted] in "lost profits" resulting from Bayer's allegedly "blocking" the Breast AI trial for registration in Europe. (Ex. 60 at ¶13.2) Onyx's claim cannot survive, as Bayer has *agreed* to proceed with and fund its share of that trial. (Ex. 51) Onyx's damages expert, Dr. Cockburn, concedes that if the Breast AI trial is "green-lighted, then there's a different allegation as to liability, and a different damages analysis would be appropriate." (Cockburn Dep. 110:16-11:11, Ex. 66) In other words, the only theory of liability and damages that Onyx has presented—that Bayer's actions permanently precluded the development of Nexavar in Europe as combination therapy with an AI—is not true. Bayer is entitled to summary judgment on Onyx's claim regarding the alleged "blocking" of the Breast AI trial for Europe.

C. Onyx Cannot Recover "Cannibalization" Damages Because It Cannot Establish Breach of the Non-Compete Clause

Onyx's damages expert opines that "[i]f the development of DAST in and of itself was a breach of the Agreement, assuming DAST is only approved to treat GIST [a type of gastric cancer], damages are [redacted]." (Ex. 60 at ¶98.2) Dr. Cockburn's theory is that DAST will "cannibalize" Nexavar sales in kidney and liver cancer through "off-label" prescriptions. (*Id.*

¶¶13.2-13.4)[9] This cannibalization claim is only sustainable if DAST is not a Collaboration Compound. If Onyx were to prevail on its claim that DAST is a Collaboration Compound, Onyx would recover any Nexavar "lost profits" through its share of DAST.

But because DAST is not a Collaboration Compound, then the only possible basis for liability supporting "cannibalization" damages would be a claim that Bayer is not permitted to develop a compound whose off-label prescriptions might affect Nexavar sales. Onyx is not relying on any direct competition because there is none. Bayer is *not* developing DAST for kidney or liver cancer, the only indications for which Nexavar is approved. (Moeller Dep. 117:18-18:6, 119:8-23, 121:5-8, Ex. 34) Nor is Bayer developing DAST for any indication in which it has a Phase 3 clinical trial underway for Nexavar. (*Compare* Ex. 33 at 2 *with* Ex. 67)

Onyx's claim based on DAST sales resulting from off-label prescriptions fails as a matter of law. The plain language of the Agreement permits Bayer and Onyx to compete with each other after the end of the Research Term, on January 31, 1999. Section 26.3—the collaboration's non-compete clause—only prohibits competition "during the Research Term." It does not preclude "competition" in 2011 or later—more than twelve years after the conclusion of the Research Term. *See, e.g.*, *AB Group v. Wertin*, 59 Cal. App. 4th 1022, 1036-37 (1997) ("Economic efficiency is promoted when [joint venturers] are able to modify fiduciary duties to accommodate their unrelated business. (The typical example is an agreement which allows the partners to continue to compete with each other outside the partnership project.) Without that freedom, such partnerships or joint ventures might never be formed, and the jobs and wealth later created never brought into being.").

The extrinsic evidence is consistent with the plain meaning of the Agreement. The principal negotiators of the Agreement confirm that the companies intended to allow competition with each other once the collaboration concluded, and that the Agreement's non-compete restrictions are limited to the Research Term. (Brandau Dep. 237:4-23, Ex. 10; Jones Dep. 106:1-

[9] Bayer policy prohibits off-label promotion of its pharmaceutical products. In addition, Bayer takes prophylactic steps to avoid Bayer sales representatives promoting off-label.

07:2, Ex. 12) Onyx's own internal documents, created during the negotiations that preceded the execution of the Agreement, reflect Onyx's understanding at the time: that Onyx would be "competitors with Bayer at the end of [research] term," and thus should "plan for aggressive independent development." (Ex. 11 at -820-21)

Onyx has referred to Section 3.6 of the Agreement in support of its argument. (Dkt#50, 2d Am. Compl. at ¶28) This section, entitled "General" within Section 3, entitled "Management of Collaboration," states:

> In all matters related to the collaboration established by this Agreement, the Parties shall be guided by standards of reasonableness in economic terms and fairness to each of the Parties, striving to balance as best they can the legitimate interests and concerns of the Parties and to realize the economic potential of the Products. In conducting research, development, and commercialization activities under this Agreement neither Party shall prejudice the value of a Product by reason of such Party's activities outside of the Field.

(Ex. 3 at §3.6)

Section 3.6 does not prohibit competition after the Research Term. Specific provisions in a contract prevail over more general ones. *Brinderson-Newberg Joint Venture v. Pacific Erectors, Inc.*, 971 F.2d 272, 279 (9th Cir. 1992) ("It is well settled that 'where there is an inconsistency between general provisions and specific provisions, the specific provisions ordinarily qualify the meaning of the general provisions.'"). Moreover, the aspirational language of Section 3.6—with a focus on "reasonableness in economic terms," and "balanc[ing]" of interests—must "give way in case of conflict with the operative provisions of [the] contract": in this instance, Section 26.3. *Gulf Oil Corp. v. Federal Power Comm'n*, 563 F.2d 588, 598 (3d Cir. 1977).

In fact, Onyx has agreed that Section 3.6 does not bar competition. Onyx's lead negotiator Bob Jones testified that he did not view Section 3.6 as a non-compete. (Jones Dep. 103:9-11, Ex. 12) Onyx's lawyers have admitted that Onyx does not "interpret[] Article 3.6 as a broad prohibition against pursuing anti-cancer programs." (Ex. 68) Onyx could not take a different position given that it is developing its own anti-cancer drugs. (Ex. 69) For this reason, Onyx's claim that it will hypothetically be injured by "off-label" competition from DAST (if DAST ever gains FDA approval) fails as a matter of law.

III. ONYX CANNOT PROVE WITH REASONABLE CERTAINTY THAT IT HAS INCURRED DAMAGES

Onyx's claims for [redacted] in lost profits damages fail as a matter of law for a separate reason—it cannot show that it will incur these lost profits damages with "reasonable certainty." Even assuming liability, it is undisputed that there is at least a 43 percent chance that Onyx will not incur any damages in each claimed cancer indication (based on Onyx's own expert opinions) because Nexavar may not be approved for that indication. As a matter of law, a 43 percent chance of no damages is not reasonable certainty. For this reason, Bayer is entitled to summary judgment on each of Onyx's first three claims to the extent that it seeks damages.

A. Uncertainty As To the Fact of Whether Any Damages Were Sustained At All Is Fatal to Recovery

"It has long been settled in California that 'the proof must establish with reasonable certainty and probability that damages will result in the future to the person wronged.'" *Vestar Dev. II, LLC v. General Dynamics Corp.*, 249 F.3d 958, 961 (9th Cir. 2001) (citations omitted); *Green Wood Indus. Co. v. Forceman Int'l Dev. Group, Inc.*, 156 Cal. App. 4th 766, 776 (2007) ("a loss reasonably certain to occur in the future") (citations omitted).[10]

"Lost anticipated profits cannot be recovered if it is uncertain whether any profit would have been derived at all from the proposed undertaking." *S. C. Anderson, Inc. v. Bank of Am.*, 24 Cal. App. 4th 529, 535 (1994). "Uncertainty as to the fact of whether any damages were sustained at all is fatal to recovery." *Fisher v. Hampton*, 44 Cal. App. 3d 741, 748 (1975). In *Fisher*, a general partner in an oil exploration limited partnership breached his agreement to drill an exploratory well on a lease that the limited partnership acquired. *Id*. at 746. The court denied recovery. "Since appellants sought damages based on the profits lost from the failure to drill one well, it was incumbent upon them to establish those damages with reasonable certainty." *Id*. at

[10] Reasonable certainty refers to the fact to be proved, not the quantum of proof required, and courts routinely distinguish the concepts. *Boyer v. Wells*, No. B205345, 2008 WL 3984342 (Cal. Ct. App. Aug. 29, 2008) ("Where evidence of damages is speculative and would not allow a trier of fact to find with reasonable certainty the existence of damages by a preponderance of the evidence, summary judgment is proper."); *Hill v. United States*, No. C00-4620 BZ, 2002 WL 826790 (N.D. Cal. Apr. 29, 2002) ("I find that the plaintiff has established by a preponderance of the evidence, the reasonable certainty of the following damages….").

750; *see also Kids' Universe v. In2Labs*, 95 Cal. App. 4th 870, 887-88 (2002) (affirming summary judgment of no lost profits damages sought by plaintiff web-site developer because "the evidence, while *suggesting* the Web site would have been viable, is not of a type necessary to demonstrate that a triable controversy exists as to a reasonable certainty that the unestablished business would have made a *profit*." (emphasis in original)).

In a pharmaceutical case involving a new drug not yet approved by the FDA, a federal court in a different circuit ruled that "inherent uncertainty makes the recovery of lost profits for anticipated sales of a new drug exceedingly difficult." *Alphamed Pharm. Corp. v. Arriva Pharm. Inc.*, 432 F. Supp. 2d 1319, 1346 (S.D. Fla. 2006), *aff'd*, 294 F. App'x. 501 (11th Cir. 2008).

B. There is At Least a 43 Percent Chance Onyx Has Incurred Zero Damages

As to each of Onyx's three damages theories (CRC KRAS, Breast AI and off-label cannibalization by DAST), Onyx's damages expert, Professor Iain M. Cockburn assumes a 43 percent chance that there would be no approval, based on PTRS numbers that he obtained from Onyx's drug development expert Robert Mass: 1) a 43 percent chance Nexavar would not be approved for CRC KRAS; 2) a 43 percent chance Nexavar would not be approved for Breast AI; and 3) a 43 percent chance DAST would not be approved and cannibalize Nexavar sales. (Ex. 60, ¶70, fn. 117)

Professor Cockburn conceded that his lost profits calculations imply a 43 percent probability that Onyx has not suffered injury:

> Q: In your model, mathematically, it's as if there's a 57 percent chance that you get the full damages, and a 43 percent chance that there are zero damages, correct?
>
> A: It's mathematically equivalent….

(Cockburn Dep. 108:19-09:5, Ex. 66) He further admitted, "if you want to phrase it as 43 percent of the time there's no damages, and 57 percent of the time there's nonrisk-adjusted level of damages, then that's another way to think about it." (*Id*. 105:25-06:4) Dr. Mass, from whom Prof. Cockburn imported the 57 percent assumption, agreed that this means there is a "43 percent chance that Nexavar won't get approval for those indications." (Mass Dep. 101:10-17, Ex. 70)

C. A 43 percent Chance of Zero Damages is Not Reasonable Certainty of Damages As a Matter of Law

There is no dispute that there is at least a 43 percent chance that Onyx will incur zero damages. Thus, whether Onyx will incur future lost profits is "essentially a coin toss." (Rao Dep. 121:15-22, Ex. 71) That is not reasonable certainty as a matter of law.

California courts long have recognized that reasonable certainty is a high degree of probability. *See Matthews v. Atchison, T. & S.F. Ry. Co.*, 54 Cal. App. 2d 549, 560 (1942) ("The jury may not consider consequences which are only likely to occur. To entitle a plaintiff to recover present damages for apprehended future consequences, there must be evidence to show such a degree of probability of their occurring as amounts to a reasonable certainty that they will result from the original injury.") (citation omitted).

Under no reasonable interpretation of "reasonable certainty" does a 57 percent chance of the fact of damages rise to that level. And the 57 percent chance of damages is itself a litigation creation, as Onyx's damages expert ignores Onyx's own internal estimates that are far below 50 percent. (*E.g.*, Ex. 72 at -973; Ex. 73; Ex. 74 at -230; Ex. 75 at -353; Ex. 76 at 3; Ex. 77 at -485) But even using this inflated estimate, the probability that Onyx will incur zero damages is still far too high—43 percent—to satisfy California's reasonable certainty requirement.

As the court stated in *Alphamed Pharm.* in the context of a new drug, "the commercial success of a new venture should be determined in the marketplace, not in the courtroom. An endorsement of the alternative would permit start-up corporations to reap unearned profits without bearing the costs and risks that every other entrepreneur must shoulder." 432 F. Supp. 2d at 1340. Onyx seeks just such unearned profits here. The Court should grant Bayer summary judgment on Onyx's claims for damages.

CONCLUSION

For the foregoing reasons, Bayer requests that the Court grant summary judgment against Onyx on the claims in Onyx's Second Amended Complaint.

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APPENDIX A

Collaboration Agreement Deadlines vs. DAST Testing